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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,455	01/14/2005	Helmut Goldmann	26569U	8794

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THE NATH LAW GROUP
112 South West Street
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EXAMINER	
SCHILLINGER, ANN M	

ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
02/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,455	GOLDMANN, HELMUT	
	Examiner	Art Unit	
	ANN SCHILLINGER	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,27,28,30 and 32-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,27,28,30 and 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18, 27, 28, 30, and 32-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Amended claim 18 states that the silver layer is made exclusively of elemental silver. However, the Applicant's specification only states that the silver layer is *preferably* made of *pure* elemental silver, thus not complying with the written description requirement.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18, 27, and 32-34 are rejected under 35 U.S.C. 103(a) as being anticipated by Trogolo et al. (U.S. Pat. No. 6,296,863) in view of Bates et al. (U. S. Pat. No. 6,530,951). Trogolo et al. discloses the following of claim 18: a vascular prosthesis (col. 1, lines 28-37) for replacement of hollow organs with antibiotic long-term action with a basic structure which

defines the form of the prosthesis and which is made of substantially non-absorbable or only slowly absorbable polymer material (10, 18; col. 3, lines 2-4, 15-21) and of a coating of an absorbable material (col. 8, lines 31-40), with a layer of metallic silver (20; col. 3, lines 66 through col. 4, lines 30) situated on the polymer material and underneath the coating (col. 8, lines 9-22, 31-40 indicates that the collagen coating disclosed above is added last over the base and the silver layer). Also Trogolo et al. discloses the prosthesis' porosity in col. 2, lines 56 through col. 3, lines 2 and col. 8, lines 18-33. Trogolo et al. does not disclose using elemental silver to serve as the layer on the prosthesis. However, Bates et al. teaches an implantable medical device that has layers of elemental silver in col. 3, lines 30-45 and col. 4, line 59 through col. 5, line 10 for the purpose of utilizing the material's antibacterial properties. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use elemental silver layers in order to utilize the material's antibacterial properties.

Regarding the ranges of thickness and decomposition rates, it would have been obvious to one having ordinary skill in the art at the time the invention was made to create a silver layer with the claimed properties, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

Regarding the use of vapor-deposition to distribute the silver atoms, it has been held that a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S.P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re

Klug, 333 F2d 905, 142 U.S.P.Q. 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 353 F2d 67, 190 U.S.P.Q. 15, see footnote 3 (CCPA 1976).

Trogolo et al. discloses the following of claim 27: the prosthesis as claimed in claim 18, wherein the absorbable coating is formed from optionally crosslinked biological material (col. 8, lines 31-33).

Trogolo et al. discloses the following of claim 32: the prosthesis as claimed in claim 31, wherein the fibers of the textile basic structure are coated with silver at least at the locations which point toward at least one surface of the prosthesis (see Figure 4).

Trogolo et al. discloses the following of claim 33: the prosthesis as claimed in claim 32, wherein substantially the entire surface of the fibers being coated with silver (see Figure 4).

Trogolo et al. discloses the following of claim 34: the prosthesis as claimed in claim 18, wherein the basic structure is made from a sintered material (col. 3, lines 2-4).

Claims 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trogolo et al. in view of Bates et al., as shown in claim 18, further in view of Shikani et al. (U. S. Pat. No. 5,762,638). Regarding claim 28, Trogolo et al., as modified by Bates et al., does not disclose using a synthetic polymers as the absorbable coating on the outside of the prosthesis. In the field of medical devices, Shikani et al. teaches in col. 14, lines 8-25, 37-47 that synthetic polymers and co-polymers make excellent coating materials on prosthetic devices because they are not prone to swelling and are non bioerodible. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to potentially replace Trogolo et al.'s

collagen coating with a synthetic polymer as both are known in the art to have properties that are necessary for coatings on prosthetics.

Regarding claim 30, Trogolo et al., as modified by Bates et al., does not disclose using active substances in the absorbable coating. Shikani et al. teaches in col. 5, lines 47-62 that it is known in the art to place drugs in the outer coating of a device such that it can be programmed to be released after a certain period of time based on the choice of the outer coating. This will help prevent inflammation and granulation tissue at the sites where these prosthetics are implanted. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use such an outer coating on Trogolo et al.'s prosthesis to prevent inflammation and granulation tissue at the site of implantation. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to choose a coating that is absorbed after four months at the latest, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

Applicant's arguments filed 11/21/2008 have been fully considered but they are not persuasive. The Bates et al. reference describes using elemental silver, and does not state that this silver layer will include other compounds. The Applicant has argued that it would not be obvious to one having ordinary skill in the art to combine the Trogolo et al. and the Bates et al. references. However, the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). An assertion of what seems to follow from common

experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness. See MPEP § 716.01(c).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3774

/William H. Matthews/
Primary Examiner, Art Unit 3774